

## REMARKS

Claims 1-42 were pending in the application. No claims have been amended or canceled. Accordingly, claims 1-42 will remain pending.

No new matter has been added. Any cancellation of the claims should in no way be construed as an acquiescence to any of the Examiner's rejections and was done solely to expedite the prosecution of the application. Applicant reserves the right to pursue the claims as originally filed in this or a separate application(s).

### *Rejection of Claims 1-42 Under 35 USC 103(a)*

The Examiner has rejected claims 1-42 under 35 USC 103(a) as being unpatentable over Ueno and Yano et al. Applicant traverses this rejection.

The Examiner states that Ueno teaches "the use of n-6 fatty acids containing oil and N-3 fatty acids containing oil such as DHA and EPA in pharmaceutical formulations for the treatment of dry eye or dry mouth syndrome." Applicant considers that the Examiner has misread the Ueno patent and that this statement is not accurate. At most, Ueno teaches that "fatty acid derivatives" can be used to treat dry eye. While the fatty acid derivatives may have any fatty acid as their base structure, the derivatives are not DHA or EPA itself. All that is possibly enabled in Ueno is what is shown in the claims and the examples; the use of certain prostaglandins that are derived from fatty acids, not the fatty acids themselves. In contrast, the claims provide for a nutritional supplement containing a n-6 fatty acid containing oil and a n-3 rich oil, wherein the n-3 rich oil contains a high concentration of eicosapentaenoic acid (EPA) and a high concentration of docosahexaenoic acid (DHA). These are the fatty acids themselves, not derivatives of the fatty acids as described in Ueno.

The instant invention is based on the identification that the combination of n-3 rich oils containing high concentrations of DHA and EPA fatty acids with an n-6 fatty acid containing oil effectively treats dry eye and related conditions. DHA and EPA are fatty acids that are present in a number of oils, primarily from fish oils and certain other oils, but they are not present in all oils. Further, many of the oils that do contain both DHA and EPA do not contain high levels of these fatty acids.

Ueno does not teach or suggest n-3 fatty acids containing high concentrations of EPA and DHA. Rather, Ueno merely lists a number of fatty acids that can be used in the methods of the invention and does not provide teachings about specific combinations which are clinically effective. The oils listed in Ueno, which form the basis of the derivatives describe, include not just DHA and EPA but also arachidonic acid, linoleic acid and other n-6 oils. There is nothing to suggest that there is anything special about DHA or EPA per se; in fact, as noted, Ueno does not use the oils themselves. Ueno does not teach the specific combination of EPA and DHA in n-3 rich oils at all. Moreover, Ueno does not teach or suggest that high concentrations of these specific fatty acids are beneficial for the treatment of dry eye and related conditions.

The secondary reference cited by the Examiner, Yano et al., does not make up for the deficiencies of Ueno. Yano et al. teach that the combination of vitamin E and DEA can modulate cell apoptosis induced by TNF. Yano does not teach the combination of oils rich in DEA and EPA with vitamin E nor the addition of n-6 containing oils. Moreover, Yano et al. is directed to inhibiting apoptosis induced TNF. Yano et al. does not teach or suggest the use of EPA and vitamin E for the treatment of the conditions set forth in the instant claims, and therefore, even if Yano et al. did teach a combination of the claimed fatty acids with vitamin E, one of skill in the art would not think to apply these teachings to the treatment of disorders such as dry eye.

Even if Yano et al. had provided teachings related to the use of EPA and vitamin E for the treatment of dry eye, the combination of Yano et al. and Ueno would still fail to render the instant invention obvious. The instant invention is based on the identification that the combination of n-3 rich oils containing high concentrations of DHA and EPA fatty acids in combination with an n-6 fatty acid containing oil effectively treat dry eye and related conditions. Therefore, the combination of the teachings of Yano et al. and Ueno do not lead one of ordinary skill in the art to the claimed invention.

Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the foregoing rejection.

### CONCLUSION

In view of the above amendment, Applicants believe the pending application is in condition for allowance. If a telephone conference would expedite allowance of this application, the Examiner is urged to call the undersigned.

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Respectfully submitted,

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